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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,825	03/22/2001	Keith D. Allen	R-849	6413
26619	7590	04/07/2004	EXAMINER	
DELTAGEN, INC. 740 BAY ROAD REDWOOD CITY, CA 94063			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/815,825

**Applicant(s)**

ALLEN ET AL.

**Examiner**

Daniel M Sullivan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2003 and 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

This Non-Final Office Action is a reply to the Papers filed 17 December 2003 and 16 January 2004 in response to the Non-Final Office Action mailed 26 August 2003. Claims 1-5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 were considered in the 26 August Office Action. Claims 1-3, 5, 8, 10-12, 23, 32, 33, 35 and 42 were amended in the 16 January Paper. Claims 1-5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 are pending and under consideration.

### ***Response to Amendment***

#### Claim Objections

Objection to claim 1 as containing informalities is withdrawn.

#### Claim Rejections - 35 USC § 112, First Paragraph

Rejection of claims 10, 11, 12, 23 32 and 35 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendment such that they are now limited to the subject matter enabled by the disclosure.

Rejection of claims 5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the limitation of the disruption of the claims to the absence of functional cGMP phosphodiesterase alpha subunit.

Rejection of claims 1-3 and 32 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

### *New Grounds*

#### Double Patenting

Applicant is advised that should claim 12 be found allowable, claims 27 and 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, each of the claims is directed to a method limited to comprising the steps of administering an agent to the transgenic mouse of claim 8 and determining whether an eye abnormality of the transgenic mouse is ameliorated. There is no discernable difference in the scope of the claimed methods.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the claims omit essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Selecting a cell which has undergone homologous recombination following the step of introducing the targeting construct and prior to the step of introducing the cell into a blastocyst.

The claims are further indefinite in reciting in step (c), “said pseudopregnant mouse gives birth”. Once the blastocyst has been implanted in the pseudopregnant mouse the mouse is no longer pseudopregnant. The mouse is actually pregnant. Amending step (c) to read “...wherein said mouse gives birth...” would be remedial.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Qin *et al.*

(1992) *J. Biol. Chem.* 267:8458-8463.

Although it was previously indicated that the claims were free of the art, upon further consideration it is apparent that the targeting construct of claim 1 and the method of producing a targeting construct of claim 3 read on any nucleic acid comprising a nucleic acid encoding a cGMP phosphodiesterase and selectable marker because the selectable marker can be anywhere in the construct and the first and second sequences homologous to the cGMP phosphodiesterase alpha subunit gene are not limited to being non-contiguous. Thus, the nucleic acid construct

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comprising a mouse cGMP phosphodiesterase and selectable marker gene, and method of making said nucleic acid construct, taught by Qin *et al.* anticipates the claims (see especially the second full paragraph on page 8459 and Figure 1 and the caption thereto.

Amending the claim to indicate that the first and second polynucleotide sequences homologous to the target gene are interrupted by the selectable marker gene and to indicate that the first and second sequences are inserted such that they flank the marker gene would overcome this rejection.

#### ***Allowable Subject Matter***

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4, 5, 8-12, 17-23, 27-33, 35, 42, 45 and 47 are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

*Anne-Marie Falk*  
**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**